

Clinical Screw, Abutment Screw, Prosthetic Screw

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

A pre-manufactured device to be directly connected to the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.

The Clinical Screw, Abutment Screw and Prosthetic Screw are made of titanium alloy Ti-6Al-4V and certain configurations have DLC (Diamond Like Carbon) coating.

Intended use:

The Clinical Screw, Abutment Screw and Prosthetic Screw are intended to secure a dental abutment or framework to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

Indications:

The Clinical Screw, Abutment Screw and Prosthetic Screw are to be directly connected to the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.

Contraindications:

- It is contraindicated placing Clinical Screw, Abutment Screw and Prosthetic Screw in:
- Patients who are medically unfit for an oral surgical procedure.
 - Patients who are allergic or hypersensitive to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) or DLC (Diamond Like Carbon) coating.

Cautions:

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.

Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy.

In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Never exceed the recommended maximum prosthetic tightening torque. Over tightening may lead to screw fracture.

Handling procedure:

1. Select appropriate screw for the abutment or framework. Correct choice of screw can be found in the respective Instructions for Use for the prefabricated or NobelProcera® abutment or framework.
2. Following conventional procedures insert the screw into the abutment or framework and place the assembly onto the implant.
3. Tighten the Clinical Screw, Abutment Screw or Prosthetic Screw using the screwdriver and torque wrench or drilling device. Correct choice of tooling (e.g. screwdriver and torque wrench) and the recommended maximum prosthetic tightening torque can be found in the respective Instructions for Use for the prefabricated or NobelProcera® abutment or framework.

Caution: Never exceed recommended maximum tightening torque detailed in applicable Instructions for Use for the abutment or framework for the Clinical Screw, Abutment Screw and Prosthetic Screw. Overtightening of abutment may lead to screw fracture.

Materials:

Titanium alloy 90% Ti, 6% Al, 4% V with or without DLC (Diamond Like Carbon) coating.

Cleaning and sterilization:

The Clinical Screw, Abutment Screw and Prosthetic Screw are delivered non-sterile for single use. Prior to use clean, disinfect and sterilize the product using the recommended parameters.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

Caution: This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.

For USA: Seal single device in a pouch and steam sterilize at 270°F, max 279°F (132°C, max 137°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C, max 137°C (270°F–275°F, max 279°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C, max 137°C (273°F–275°F, max 279°F) for 3 minutes.

Full set of recommended parameters are provided in “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Magnetic Resonance (MR) safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada – License Exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription Device – Rx Only

Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.



Rx Only



Non-sterile



Consult instructions for use



Do not re-use



Batch code



Do not use if package is damaged

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